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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/844,861	04/27/2001	Muralidhara Padigaru	15966-789 (CURA 289)	1375

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EXAMINER	
NICKOL, GARY B	
ART UNIT	PAPER NUMBER
1642	18

DATE MAILED: 07/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/844,861	PADIGARU ET AL.	
	Examiner	Art Unit	
	Gary B. Nickol Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-52 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-52 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 1-52 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, 38, and 41, drawn to ONE isolated polypeptide, pharmaceutical composition and kit thereof, classified in class 530, subclass 350.

(The above Group includes 28 possible polypeptides each of which comprises an independent and distinct invention; not a species. Upon election, applicant should indicate the polypeptide by SEQ ID NO.)

II. Claims 5-14, 39, and 42, drawn to ONE isolated nucleic acid, vectors, host cells, pharmaceutical compositions and kit thereof, classified in class 536, subclass 23.5; class 435, subclasses 320.1, 325.

(The above Group includes 28 possible polynucleotides each of which comprises an independent and distinct invention; not a species. Upon election, applicant should indicate the polynucleotide and corresponding encoded polypeptide by SEQ ID NO.)

III. Claims 15-17, 40, 43, drawn to ONE isolated antibody, pharmaceutical composition and kit thereof, classified in class 530, subclass 387.1.

(The above Group includes 28 possible antibodies each of which comprises an independent and distinct invention; not a species. Upon election, applicant should indicate the polypeptide by SEQ ID NO. to which the antibody binds to)

IV. Claim 18, drawn to a method for determining the presence or amount of ONE polypeptide in a sample comprising contacting the sample with an antibody and determining the presence or amount of antibody bound to said polypeptide, classified in class 435, subclass 7.1.

(The above Group includes 28 possible polypeptides each of which comprises an independent and distinct invention; not a species. Upon election, applicant should indicate the polypeptide by SEQ ID NO.)

V. Claims 19-21, drawn to a method for determining the presence or amount of ONE nucleic acid molecule in a sample comprising contacting the sample with a probe and determining the presence or amount of the probe bound to said nucleic acid, classified in class 435, subclass 6.

(The above Group includes 28 possible polynucleotides each of which comprises an independent and distinct invention; not a species. Upon election, applicant should indicate the polynucleotide and corresponding encoded polypeptide by SEQ ID NO.)

VI. Claims 22-24, drawn to a method of identifying an agent that binds to ONE polypeptide comprising contacting said polypeptide with said agent and determining whether said agent binds to said polypeptide, classified in class 435, subclass 4.

(The above Group includes 28 possible polypeptides each of which comprises an independent and distinct invention; not a species. Upon election, applicant should indicate the polypeptide by SEQ ID NO.)

VII. Claim 25, drawn to a method of modulating the activity of ONE polypeptide comprising contacting a cell sample expressing said polypeptide with a compound that binds to said polypeptide in an amount sufficient to modulate the activity of the polypeptide, classified in class 435, subclass 7.1.

(The above Group includes 28 possible polypeptides each of which comprises an independent and distinct invention; not a species. Upon election, applicant should indicate the polypeptide by SEQ ID NO.)

VIII. Claims 26-29, 48, drawn to a method of treating or preventing a GPCRX-associated disorder comprising administering ONE polypeptide to a subject or mammal, classified in class 424, subclass 184.1.

(The above Group includes 28 possible polypeptides each of which comprises an independent and distinct invention; not a species. Upon election, applicant should indicate the polypeptide by SEQ ID NO.)

IX. Claims 30-33, drawn to a method of treating or preventing a GPCRX-associated disorder comprising administering ONE nucleic acid to a subject, classified in class 514, subclass 44.

(The above Group includes 28 possible polynucleotides each of which comprises an independent and distinct invention; not a species. Upon election, applicant should indicate the polynucleotide and corresponding encoded polypeptide by SEQ ID NO.)

X. Claims 34-37, 49, drawn to a method of treating or preventing a GPCRX-associated disorder comprising administering ONE antibody to a subject or mammal, classified in class 424, subclass 130.1.

(The above Group includes 28 possible antibodies each of which comprises an independent and distinct invention; not a species. Upon election, applicant should indicate the polypeptide by SEQ ID NO. to which the antibody binds to.)

XI. Claims 44-45, drawn to a method for determining the presence or predisposition to a disease associated with altered levels of ONE polypeptide, comprising measuring the expression level of said polypeptide in a sample from a first subject; comparing said expression to controlled samples, wherein an alteration in the expression level of said polypeptide in said first subject compared to

controlled samples indicates the presence of disease, classified in class 435, subclass 7.23; class 424, subclass 9.1.

(The above Group includes 28 possible polypeptides each of which comprises an independent and distinct invention; not a species. Upon election, applicant should indicate the polypeptide by SEQ ID NO.)

XII. Claims 46-47, drawn to a method for determining the presence or predisposition to a disease associated with altered levels of ONE nucleic acid, comprising measuring the expression level of said nucleic acid in a sample from a first subject; comparing said expression to controlled samples, wherein an alteration in the expression level of said nucleic acid in said first subject compared to controlled samples indicates the presence of disease, classified in class 435, subclass 6; class 424, subclass 9.1.

(The above Group includes 28 possible polynucleotides each of which comprises an independent and distinct invention; not a species. Upon election, applicant should indicate the polynucleotide and corresponding encoded polypeptide by SEQ ID NO.)

XIII. Claim 50, drawn to a method for the screening of a candidate substance interacting with ONE olfactory receptor polypeptide comprising bringing into contact said polypeptide with said candidate substance and detecting the complexes formed, classified in class 435, subclass 4.

(The above Group includes 28 possible polypeptides each of which comprises an independent and distinct invention; not a species. Upon election, applicant should indicate the polypeptide by SEQ ID NO.)

XIV. Claim 51, drawn to a method for detecting the production level of second messenger metabolites, said method comprising the screening of ligand molecules interacting with ONE olfactory receptor polypeptide comprising providing a recombinant eukaryotic host cell containing a nucleic acid encoding said polypeptide, preparing membrane extracts of said host cell, bringing into contact said extracts with selected ligand molecules, and detecting the production level of second messenger metabolites, classified in class 435, subclass 4.
(The above Group includes 28 possible polynucleotides each of which comprises an independent and distinct invention; not a species. Upon election, applicant should indicate the polynucleotide and corresponding encoded polypeptide by SEQ ID NO.)

XV. Claim 52, drawn to a method for the screening of ligand molecules interacting with ONE olfactory receptor polypeptide comprising providing an adenovirus containing a nucleic acid encoding said polypeptide, infecting an olfactory epithelium with said adenovirus, bringing into contact said olfactory epithelium with a selected ligand molecule, and detecting the increase of the response to said ligand molecule, classified in class 435, subclass 5.

(The above Group includes 28 possible polynucleotides each of which comprises an independent and distinct invention; not a species. Upon election, applicant should indicate the polynucleotide and corresponding encoded polypeptide by SEQ ID NO.)

The inventions are distinct, each from the other because of the following reasons:

The Inventions of Groups I-III represent separate and distinct products which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects.

The inventions of Groups IV-XV are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

The invention of Group I and the methods of Groups IV, VI-VIII, XI, and XIII-XV are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the polypeptide product as claimed can be used in a variety of materially different process such as affinity chromatography, methods of treating a GPCRX-associated disorder, and the screening of ligand molecules interacting with olfactory receptor polypeptides.

The invention of Group II and the methods of Groups V, IX, XII, and XIV-XV are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the nucleic acid product as claimed can be used in a variety of materially different process such as affinity chromatography, gene therapy, and the screening of ligand molecules interacting with nucleic acids encoding olfactory receptor polypeptides.

The invention of Group III and the methods of Groups IV and X are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the nucleic acid product as claimed can be used in a variety of materially different process such as affinity chromatography, or methods of treating a GPCRX-associated disorder.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, because these inventions are distinct for the

reasons given above and the search required for one group is not required for another group, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol, Ph.D.
Examiner
Art Unit 1642

GBN
July 2, 2003

Gary B. Nickol